BRITISH MEDICAL JOURNAL

10.5281/zenodo.6481100
British Medical Journal
Volume 2, No 1., 2022
Internet address: http://ejournals.id/index.php/bmj
E-mail: info@ejournals.id
Published by British Medical Journal
Issued Bimonthly
3 knoll drive. London. N14 5LU United Kingdom
+44 7542 987055
Chief Editor
Dr. Fiona Egea

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British Medical Journal Volume-2, No 1
10.5281/zenodo.6481100

SOFT AND HARD GELATIN CAPSULES FOR THE PREVENTION AND TREATMENT OF VIRAL INFECTION

Shaykhova Guli Islamovna,
Professor, Doctor of Medical Sciences, Department of Hygiene of Children, Adolescents and Nutritional Hygiene, Tashkent Medical Academy (Tashkent)
E-mail. guli.shayhova@gmail.com
Ortikov Bobomurod
Assistant of the Department of Hygiene of Children, Adolescents and Nutritional Hygiene of the Tashkent Medical Academy, Tashkent, Uzbekistan
E-mail. bobomurodortiqov89@gmail.com
Zokirkhonova Shahzoda Azatovna
Associate Professor of the Department of Pediatric Therapeutic Dentistry, Tashkent State Dental Institute

Abstract. Based on the results of our own research, the new food product has been developed – prophylactic soft and hard gelatin capsules - sedan bark and ginger, production of "SHANAZ" LLC(Uzbekistan). Contains a sufficient amount of protein, minerals, vitamins and dietary fiber. A study of efficacy in patients with coronavirus showed weight loss; decrease in appetite; refreshing of the digestive organs; removal of metabolic products and other toxins; normalization of metabolism; improvement of hematological parameters, decrease the concentration of liver enzymes (AST, ALT and GGT) in plasma, as well as total bilirubin, which characterize the detoxification activity of the liver, decrease in the concentration of total cholesterol and glucose in the blood.

Keywords: food substance – preventive soft and hard gelatin capsules - sedan bark, ginger for patients with coronavirus, biochemical parameters

Nutrition is an important determinant of immune status, already at the beginning of the COVID-19 pandemic, the World Health Organization (WHO) identified the nutrition factor as one of the key factors in maintaining public health under quarantine and self-isolation. Public health algorithms discussed in terms of immunity and infections often lack a nutritional strategy to maintain optimal immune system function. Low body levels or intake of micronutrients such vitamins as A, E, B6, B12, C, D and zinc, selenium associated with adverse clinical outcomes in viral infections. In this regard, the development of new products for the prevention and treatment of viral infections is relevant.

Purpose of the study. Study of nutritional and biological value soft and hard gelatin capsules (sedan bark, ginger) for the prevention and treatment of viral infections.

Materials and research methods. When conducting scientific research, a set of methods was used depending on the tasks set: organoleptic, physico-chemical, biochemical, computational and statistical methods.The studies were carried out at the Department of Hygiene of Children, Adolescents and Nutritional Hygiene of the Tashkent Medical Academy (TMA), the Interuniversity Research Laboratory (INRL) of the TMA, the testing center of the Institute of Plant Substances named after Academician S.A. Yunusova of the Republic of Uzbekistan.

During the physical characteristics of the studied samples, the following indicators were studied (9): humidity, acidity, gluten (15113.4-91, 15113.5-91, 202239-91).

The chemical characteristics of the prototypes are determined by the following indicators: - crude protein - by the Kjeldal method (GOST 0846-91); total lipids - by the Rushkovsky method (GOST 0846-91); ash - after burning in a muffle furnace (A.P. Ermakov, 1972).

Evaluation of the effectiveness of a new nutrienthard gelatin capsule - sedan bark and ginger were carried out in the 1st - 2nd clinic of infectious diseases of the Zangiota district of Tashkent. Under observation were 938 patients aged from 18 to 60 suffering from coronavirus. The average age was 51.6±0.82 (Table 1).

Table 1.

The average age of patients suffering from coronavirus (in%).

Age	Women, n=563	Men, n=375	Total number, n=938
>18	26 (4.56)	13(3.46)	39(4.16)
18-29	34 (6.08)	20 (5.33)	54 (5.75)
30-39	53 (9.5)	62 (16.53)	115(12.26)
40-59	221 (39.2)	152 (40.53)	373(39.76)
60<	229(40.68)	128(34.13)	357(38.05)

During the treatment period, body weight, BMI, waist and hip circumference were assessed. In the clinic, together with doctors, a clinical and outpatient examination was carried out, which included a biochemical blood test with the determination of hemoglobin in the blood, erythrocytes, its serum ALT, AST, urea, creatinine and other indicators in the urine. The study was carried out at the beginning and at the end of diet therapy.

The data obtained during the study were subjected to statistical processing on a Pentium-IV personal computer using the Microsoft Office Excel-2013 software package, including the use of built-in statistical processing functions.

Research results and discussion. We, together with the employees of SHANAZ LLC, have developed food substances - hard gelatin capsules - sedan bark and ginger, produced from oils, obtained by pressing with additives from minerals, vitamins, plant extracts, as well as other substances by mixing and further producing them in the form of soft and hard capsules. (1).

When studying the organoleptic indicators and nutritional value of soft and hard gelatin capsule - "sedan bark" it was found that the form of release of gelatin capsules is soft and hard, the predominance of the color of the composition of raw materials and oils, the smell - characteristic of this type of product, prevailing in the composition of raw materials. In table 2, the information about nutritional value of "sedan bark" is given.

Table 2.

Nutritional value of hard gelatin capsule "Sedan bark" M±m

Nutrients	**Unit of measure**	
Calories	kcal	333.0±1.856
Proteins	gr	19.8±0.688
Fats	gr	14.6±0.465
Carbohydrates	gr	11.91±0.663
Alimentary fiber	gr	38±0.695
Water	gr	10±0.397
Ash	gr	5.877±0.16

A nutritional study has shown that sedan bark hard gelatin capsules have protein (g) 19.8±0.68, fat (g) 14.6±0.465, carbohydrates (g) 11.91±0.663; dietary fiber (g) (38±0.695). Calorie content is (kcal) 333.0 ± 1.856.

Individual vitamins (A, B6, C, D, E) and minerals: zinc, iron, selenium, magnesium, copper, etc. play an important and complementary role in supporting both the innate and adaptive immune systems. (14-18).

100 g of sedan bark contains the following vitamins: vitamin A - 18±0.457; Vitamin B1, thiamine - 0.383±0.04; vitamin C 21±0.535; vitamin E 2.5±0.137, vitamin E (alpha tocopherol) 2.5±0.137; vit. PP – 3.6066±0.205. (Table 3).

Table 3

Vitamin content in sedan bark(black cumin), M±m

Vitamins		

Vitamin A,	mkg	18±0.457
Vitamin B1, thiamine	mg	0.383±0.04
Vitamin C, ascorbic	mg	21.0±0.535
Vitamin D, calciferol	mkg	0±0.0
Vitamin E, alpha tocopherol	mg	2.5±0.137
Vitamin K, phylloquinone	mkg	0±0.00
Vitamin PP, NE	mg	3.6066±0.205

In addition, the food substance contains the following minerals: potassium (mg) - 1351±11.931; calcium, Ca (mg) -689±11.661; magnesium, Mg (mg) - 258±4.112; sodium, Na (mg) - 17±0.347; phosphorus, P (mg) - 568±7.425; iron, Fe (mg) - 16.23±0.241; selenium, Se (μg) - 12.1±0.254; zinc, Zn (mg) - 5.5±0.113 (Table 4).

Table 4

The content of minerals in "sedan bark" (black cumin), M±m

Name of chemical elements		
Macronutrients	**Unit.**	
Potassium, K	mg	1351±11.931
Calcium Ca	mg	689±11.661
Magnesium	mg	258±4.112
Sodium, Na	mg	17±0.347
Phosphorus, P	mg	568±7.425
Microelements		
Iron, Fe	mg	16.23±0.241
Selenium, Se	mkg	12.1±0.254
Zinc, Zn	mg	5.5±0.113

A technological instruction has been developed for this product - “Drinking soft and hard gelatin capsules”. TI 202224500-7:2019, approved by the Ministry of Health of the Republic of Uzbekistan and GOST standard of the Republic of Uzbekistan (2).

At the next stage, we also studied the nutritional value of the ginger soft gelatin capsule.

Organoleptic characteristics and nutritional value of soft and hard gelatin capsule - "ginger" has the same shape as the bark of a sedan, colors and smell - characteristic of this type of product, predominant in the composition of raw materials. In table. 5 is the nutritional value of "ginger".

Table 5

Nutritional value of hard gelatin capsule "ginger" M±m

Nutrients	**Unit.**	
Calories	kkal	80±1.445.
Proteins	gr	1.8±0.104
Fats	gr	0.8±0.076
Carbohydrates	gr	15.8±0.553
Alimentary fiber	gr	2±0.275
Ash	gr	0.77±0.018

When determining the nutritional value, it showed that ginger in its composition, compared with sedan bark, contains less proteins (g) 1.8±0.104, fats (g) 0.8±0.076, and carbohydrates (g) 15.8±0.553; dietary fiber (g) 2±0.275, ash (g) 0.77±0.018. Calorie (kcal) is only 80±1.445.

100 g of ginger contains the following vitamins: does not contain vitamin A and D, RE (mkg) - 0 ± 00; Vitamin B1, thiamine (mg) - 0.025±0.001; vitamin C (mg) - 0.025±0.001; Vitamin E, alpha tocopherol, TE (mg) 0.26±0.025. (Table 6).

Table 6

Vitamin concentration in ginger M±m

Name of chemical elements	**Unit of measure**	**Ginger**
Vitamin A,	mkg	0±00
Vitamin B1, thiamine	mg	0.025±0.001
Vitamin C, ascorbic	mg	5.0±0.001
Vitamin D, calciferol	mkg	0 ±0.00
Vitamin E, alpha tocopherol, TE	mg	0.26±0.025
Vitamin K, phylloquinone	mkg	0.1±0.01
Vitamin PP,	mg	0.75±0.01

The mineral content is shown in Table 7.

Table 7

The content of minerals in ginger, M±m

Name of chemical elements	**Unit.**	
Macronutrients		
Potassium, K	mg	415±2.717
Calcium Ca	mg	16±0.466
Magnesium	mg	43±0.768
Sodium, Na	mg	13±0.505
Phosphorus, P	mg	34±0.529
Chlorine, Cl	mg	0±0.00
Microelements		
Iron, Fe	mg	0.602±0.036
Selenium, Se	mkg	0.7±0.037
Zinc, Zn	mg	0.7±0.037

The nutritional substance ginger contains the following minerals: potassium (mg) -415±2.717; calcium 16±0.466; magnesium - 43±0.768; sodium -13±0.505; phosphorus -34±0.529; iron - 0.602±0.036; selenium -0.7±0.037; zinc - 0.7±0.037 (Table 6.).

A technological instruction has been developed for these products - “Soft and hard gelatin capsules”. TI 79994-01:2021, approved by the USEBiOZ of Tashkent (2).

It should be noted that vitamins and minerals are most effective for strengthening immunity. Vitamin C strengthens the immune system and protects it from viruses and bacteria,it is also needed for white blood cells that help fight infections. Vitamin E - is a powerful antioxidant. That is, a substance that acts as a natural shield for humans. The body has, as it were, "built-in" antioxidants, but sometimes they are not enough.Vitamin D is essential because: it is responsible for the blood

levels of minerals such as calcium and phosphorus, which help maintain and strengthen the musculoskeletal tissue (bones, joints, muscles, teeth), maintains the level of innate immunity; acts as a hormone (D-hormone).Zinc acts on the immune system (2).

It should be noted that hard and soft gelatin capsules have all the necessary vitamins and minerals to improve immunity in viral diseases,including COVID-19.

At the next stage of the biomedical evaluation of a new type of product gelatin capsule sedan bark and ginger appeared in order to most objectively evaluate the effectiveness conducting their clinical testing in patients suffering from coronavirus. At the first stage, the tolerance of patients to a new type of product was determined (within 3 days). After completion of this stage of the study, a more in-depth second stage of research was carried out, aimed at studying the effect of new products on the course of metabolic processes in patients with coronavirus.

Patients with coronavirus, who were under our supervision, received a standard diet No. 2 in the clinic. Purpose of appointment: to provide good nutrition, to moderately stimulate the secretory function of the digestive system, to normalize motor function.

Patients with coronavirus (31) in the clinic additionally received hard gelatin capsules of sedan bark in the morning and evening during breakfast and dinner twice a day. The next group of patients (30) ginger hard gelatin capsules. Patients, when they were in the clinic for 10 days, received a capsule in the clinic, after being discharged from the clinic, the patients were given a food substance free of charge for three months, prophylactic soft and hard gelatin capsules and they continued to take them at home on their own initiative.

Patients with coronavirus underwent a clinical examination: complaints, anamnesis of the disease, examination of the patient. Patients complained of weakness, headaches, dizziness, high fever, and frequent breathing.

The results of clinical studies of the effectiveness of the application gelatin capsule cortex sedan showed that within three months, in the examined patients with coronavirus, it was noted weight loss up to 3-4 kg; decrease in appetite; unloading of the digestive organs; removal of metabolic products and other toxins; normalization of metabolism; normalization of the gastrointestinal tract; improvement of the functional state of the liver and gallbladder, kidneys, skin; as well as maintaining the balance of vitamins and microelements.

According to laboratory examinations in patients with coronavirus, after taking specialized products - gelatin capsules, pronounced detoxification properties were revealed, the functions of the main organs and systems were improved, and the participation of products in the metabolism of xenobiotics and endotoxins was noted. This is confirmed by the pronounced hepatoprotective, antioxidant, hypocholesterolemic effects established in extensive clinical studies, which were revealed in laboratory studies.

In table 8 before and after admission in patients with coronavirus, the following indicators of biochemical blood were recorded.

Table 8

Biochemical parameters of patients with coronavirus when using hard gelatin capsule sedan bark

No.	**Indicators**	**Norm**	Before treatment	After treatment
1	Hb (hemoglobin)	*E; 130.0-160.0g/l A;120.0-140.0g/l*	98.6±14.45	121.17±10.66
2	(ESR)	*E; 2-10mm/coat A;2-15mm/coat*	10.0±7.98	12.33±7.42
3	WBC (leukocyte)	*4.0-9.0 109/l*	10.4±1.98	8.54±0.86

4	Lymph (lymphocyte)	*19-37%*	32.25±5.77	31.96±4.08
5	ALT	*<40*	52.83±0.98	25.33±5.49
6	AST	*thirty*	37.67±0.667	26.67±4.080
7	Glucose	*3.2-6.1mmlo/l*	5.76±0.48	4.83±0.31
eight	Urea	*2.5-8.3 mmol/l*	4.53±0.41	2.76±0.56
nine	Total protein	*46-70 g/l*	73.67±1.72	69.8±2.98
ten	Creatinine	*E:44-115μmol/l A:44-97 μmol/l*	68.06±5.08	62.5±5.52

According to clinical studies, within three months in the examined patients with coronavirus, it was noted weight loss up to 3-4, kg; decrease in appetite; unloading of the digestive organs; removal of metabolic products and other toxins; normalization of metabolism; normalization of the gastrointestinal tract; improvement of the functional state of the liver and gallbladder, kidneys, skin; as well as maintaining the balance of vitamins and microelements.

After taking specialized products - gelatin capsules after 2-3 months, patients noted a significant improvement in their condition, a decrease in pain, discomfort, and an increase in the quality of life. There was an improvement in hematological parameters, a decrease in the concentration of hepatic enzymes (AST, ALT and GGT) in the blood plasma, as well as total bilirubin, while the differences in the comparison group were minimal (Table 8).

Laboratory studies in individuals of the main group established a significant decrease in ESR and the concentration of C-reactive protein relative to the initial level. The most pronounced decrease was in the subgroup of patients, ESR and CRP concentration decreased by 16 and 13% from the initial level, respectively, and in the subgroup that received - by 34 and 26%. In all subgroups of the main group, a statistically significant decrease in the concentration of glucose by 6–17% and cholesterol by 9–18% from the initial level was revealed.

Consumption of products - a gelatin capsule of a sedan led to a significant decrease in the concentration of urea and creatinine, which indicates an accelerated removal of toxins formed in the body, metabolic products. A decrease in the concentration in the blood of the main enzymes characterizing the detoxification activity of the liver (ALT, AST) was also established. The diet with the inclusion of detoxification products provides a decrease in the content of primary and secondary LPO products (diene conjugates, ketodienes and carbonyls) against the background of an increase in total antioxidant activity, which indicates an increase in antioxidant activity and resistance to the negative effects of exogenous and endogenous factors.

Normalization of metabolic processes, expressed in a significant improvement in lipid profile and carbohydrate metabolism, in particular in a decrease in the concentration of total cholesterol and glucose in the blood, is also an important result of detoxification dietary therapy.

According to laboratory examinations in patients with coronavirus, after taking specialized products - gelatin capsules, pronounced detoxification properties were revealed, the functions of the main organs and systems were improved, and the participation of products in the metabolism of xenobiotics and endotoxins was noted. This is confirmed by the pronounced hepatoprotective,

antioxidant, hypocholesterolemic effects established in extensive clinical studies, which were revealed in laboratory studies.
Thus, developed by "SHANAZ" food substance – prophylactic soft and hard gelatin capsules -for detoxification of the body are indicated for use:
- during the period of self-isolation and quarantine in order to prevent intoxication of the body and excessive weight gain;
- in chronic diseases and their exacerbation; with a general deterioration in the state of the body, accompanied by a decrease in immunity, appetite, chronic fatigue and weakness;
- after drug therapy (antibiotic therapy, hormonal therapy and other medications);
- with psycho-emotional overstrain, frequent stress, constant negative emotional background; with the abuse of bad habits (smoking, drinking alcohol);
According to clinical studies, on average, 2 courses provide: weight loss up to 3-4 kg; decrease in appetite; unloading of the digestive organs; removal of metabolic products and other toxins; normalization of metabolism; normalization of the gastrointestinal tract; metabolism correction; improvement of the functional state of the liver and gallbladder; improvement of the functional state of the kidneys; improvement of the skin condition; maintaining the balance of vitamins and microelements.

FINDINGS

1. Soft and hard gelatin capsule - sedan bark has protein (g) 19.8 ± 0.68, fat (g) 14.6 ± 0.465, carbohydrates (g) 11.91 ± 0.663; dietary fiber (g) (38±0.695). Calorie content (kcal) 333±1.856; vitamins (A, B6, C, D, E) and minerals: zinc, iron, selenium, magnesium, copper, etc., which play an important and complementary role in supporting both the innate and adaptive immune systems.
2. Soft and hard gelatin capsule - ginger in its composition, in comparison with the bark of a sedan, contains less protein (g) 1.8 ± 0.104, fats (g) 0.8 ± 0.076, and carbohydrates (g) 15.8 ± 0.553; dietary fiber (g) 2±0.275, ash (g) 0.77±0.018. Calorie content (kkal) is only 80±1.445. vitamins (A, B6, C, D, E) and minerals: zinc, iron, selenium, magnesium, copper, etc., which play an important and complementary role in supporting both innate and adaptive immune system.
3. According to clinical studies provided: weight loss up to 3-4 kg; decrease in appetite; unloading of the digestive organs; removal of metabolic products and other toxins; normalization of metabolism; normalization of the gastrointestinal tract; metabolism correction; improvement of the functional state of the liver and gallbladder; improvement of the functional state of the kidneys; improvement of the skin condition; maintaining the balance of vitamins and microelements.
4. There was an improvement in hematological parameters, a decrease plasma concentrations of hepatic enzymes (AST, ALT and GGT), as well as total bilirubin, while in the comparison group, the differences were minimal: a decrease in the concentration in the blood plasma of liver enzymes (AST, ALT and GGT) characterizing the detoxification activity of the liver, a decrease in the concentration of total cholesterol and glucose in the blood.

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